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Registration Decision RD2014-21

Phlebiopsis gigantea strain VRA 1992

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Registration Decision for *Phlebiopsis gigantea* strain VRA 1992

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting full registration for the sale and use of Phlebiopsis gigantea strain VRA 1992 and Rotstop C, containing the technical grade active ingredient *Phlebiopsis gigantea* strain VRA 1992, to control root and butt rot, caused by *Heterobasidion irregularee*, on susceptible conifer species.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

These products were first proposed for registration in the consultation document[1] Proposed Registration Decision PRD2014-02, *Phlebiopsis gigantea* strain VRA 1992. This Registration Decision[2] describes this stage of the PMRA's regulatory process for *Phlebiopsis gigantea* strain VRA 1992 and summarizes the Agency's decision and the reasons for it. The PMRA received no comments on PRD2014-02. This decision is consistent with the proposed registration decision stated in PRD2014-02.

For more details on the information presented in this Registration Decision, please refer to the Proposed Registration Decision PRD2014-02, *Phlebiopsis gigantea* strain VRA 1992 that contains a detailed evaluation of the information submitted in support of this registration.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[3] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration. The Act also requires that products have value[4] when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

3 "Acceptable risks" as defined by subsection 2(2) of *Pest Control Products Act*.

4 "Value" as defined by subsection 2(1) of *Pest Control Products Act* "...the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact".

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

What is *Phlebiopsis gigantea* strain VRA 1992?

Phlebiopsis gigantea strain VRA 1992 is a naturally occurring saprophytic wood-rotting fungus that was isolated from a red pine stump in Harrington, Quebec. The fungus is a primary colonizer of wood, and requires high moisture content for its growth. It antagonizes the fungal pathogen *Heterobasidion irregulare* through competitive exclusion for space and nutrients. *Phlebiopsis gigantea* strain VRA 1992 is a microbial pest control agent (MPCA) in the technical product, Phlebiopsis gigantea strain VRA 1992, and the associated end-use product, Rotstop C. Rotstop C is a commercial fungicide proposed for control of root and butt rot (caused by *Heterobasidion irregulare*) in conifer trees.

Health Considerations

Can Approved Uses of *Phlebiopsis gigantea* strain VRA 1992 Affect Human Health?

***Phlebiopsis gigantea* strain VRA 1992 is unlikely to affect your health when Rotstop C is used according to the label directions.**

People could be exposed to *P. gigantea* strain VRA 1992 when handling and applying Rotstop C. When assessing health risks, several key factors are considered: the microorganism's biological properties (for example, production of toxic by-products); reports of any adverse incidents; its potential to cause disease or toxicity as determined in toxicological studies; and the level to which people may be exposed relative to exposures already encountered in nature to other isolates of this microorganism.

Toxicological studies in laboratory animals describe potential health effects from large doses in order to identify any potential pathogenicity, infectivity and toxicity concerns. When a comparative strain of *P. gigantea* (*P. gigantea* strain VRA 1835), was tested on laboratory animals, there were no signs that it caused any significant toxicity or disease. Furthermore *P. gigantea* strain VRA 1992 has an optimal growth temperature of 28°C and a maximum of 38°C. No adverse effects from *P. gigantea* strain VRA 1992 were reported in the published scientific literature.

Residues in Water and Food

Dietary risks from food and water are not of concern.

As part of the assessment process prior to the registration of a pesticide, Health Canada must determine whether the consumption of the maximum amount of residues, that are expected to remain on food products when a pesticide is used according to label directions, will not be a concern to human health. This maximum amount of residues expected is then legally established as a maximum residue limit (MRL) under the *Pest Control Products Act* for the purposes of the adulteration provision of the *Food and Drugs Act*. Health Canada sets science-based MRLs to ensure that the food Canadians eat is safe.

Phlebiopsis gigantea is ubiquitous in the forest environment and spores are commonly found in the air and on exposed surfaces. When *P. gigantea* strain VRA 1835 was administered orally to rats, no signs of toxicity or disease were observed, and no metabolites of toxicological significance have been shown to be produced by this strain of *P. gigantea*.

The end-use product has not been approved for food uses, therefore, as no residues of Rotstop C are expected on agricultural commodities, the establishment of an MRL is not required for *Phlebiopsis gigantea* strain VRA 1992. As well, the likelihood of residues contaminating drinking water supplies is negligible to non-existent. Consequently, dietary risks are minimal to non-existent.

Occupational Risks From Handling Rotstop C

Occupational risks are not of concern when Rotstop C is used according to label directions, which include protective measures.

Workers handling Rotstop C can come into direct contact with *P. gigantea* strain VRA 1992 on the skin, in the eyes or by inhalation. For this reason, the product label will specify that workers handling Rotstop C must wear waterproof gloves, long-sleeved shirts, long pants, a dust-mist filtering respirator/mask (NIOSH approval number prefix TC-21C) or a NIOSH-approved respirator (with any N-95, P-95, R-95 or HE filter for biological products), and shoes plus socks. Respiratory protection for manual application by paint brush is not required.

This personal protective equipment is not required for operators of mechanical harvesters as they work in enclosed cabs.

As a product used in forestry, bystander exposure is expected to be much less than that of handlers and mixer/loaders and is considered negligible. Therefore, health risks to bystanders are not of concern.

Environmental Considerations

What Happens When Rotstop C is Introduced Into the Environment?

Environmental risks are not of concern.

Information available in the published literature on the environmental fate of *Phlebiopsis gigantea* strain VRA 1992 suggests that, as a saprophytic fungus, the organism will establish itself well in stumps and dead wood but rarely in standing trees. Survival of *P. gigantea* strain VRA 1992 in soil is limited and populations of *P. gigantea* strain VRA 1992 in soil should return to naturally occurring levels over time.

Waivers for toxicity testing on avian species, wild mammals, arthropods, non-arthropod invertebrates as well as for freshwater fish, aquatic arthropods, and aquatic plants were deemed acceptable to address the environmental toxicological requirements for these animals. The rationales were based on the ubiquitous nature of *P. gigantea* in the forest environment and that the level of *P. gigantea* in the terrestrial and aquatic environment will not significantly increase as a result of the use of Rotstop C as a stump treatment during forestry timber harvesting. The toxicity profile of *P. gigantea* strain VRA 1992 based on laboratory animal studies also demonstrated a lack of toxicity, and a review of published literature indicated no reports of adverse effects to these terrestrial organisms, as well as a lack of adverse effects to aquatic organisms from natural populations of *P. gigantea*.

In published literature, *P. gigantea* has demonstrated a limited ability to infect living trees and does not cause adverse effects to other forest-dwelling plants.

Published literature has shown that certain types of fungi and terrestrial insects dwelling within the stumps that will be treated with Rotstop C may be temporarily affected but microbial and insect populations are expected to gradually re-establish as the natural degradation processes take place in the treated stump.

Furthermore, forestry products containing other strains of *P. gigantea* have been used in Europe for decades with no reports of adverse effects to animals.

A toxicity study has also shown that *P. gigantea* is not toxic or pathogenic to honeybees.

Value Considerations

What Is the Value of Rotstop C?

Rotstop C is a microbial fungicide that provides control of root and butt rot, caused by *Heterobasidion irregulare*, on susceptible conifer species.

Root and butt rot is considered to be one of the most economically important diseases in European temperate coniferous forests and it has the potential to significantly impact managed red pine plantations in Canada. The registration of Rotstop C will provide forest managers and woodlot owners with a fungicide option to manage this disease, as no products are currently registered for this use in Canada.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being proposed on the label of Rotstop C to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

In individuals exposed to large quantities of Rotstop C, respiratory and dermal sensitivity could possibly develop upon repeated exposure to the product since all microorganisms, including *P. gigantea* strain VRA 1992, contain substances that are potential sensitizers. Therefore, anyone handling or manually spraying Rotstop C must wear waterproof gloves, long-sleeved shirts, long pants, a dust-mist filtering respirator/mask (NIOSH approval number prefix TC-21C) or NIOSH-approved respirator (with any N-95, P-95, R-95 or HE filter for biological products), and shoes plus socks. Also, the signal words, "POTENTIAL SENSITIZER" are required on the principal display panel of *Phlebiopsis gigantea* strain VRA 1992 and Rotstop C and precautionary statements, "Avoid contact with eyes, skin and clothing," "Avoid breathing the dust or spray mist," and "May cause sensitization." are required on the secondary display panel of the label for Rotstop C.

Environment

The end-use product label will include environmental precaution statements that prevent the contamination of aquatic systems from the use of Rotstop C.

Other Information

The relevant test data on which the decision is based (as referenced in PRD2014-02, *Phlebiopsis gigantea* strain VRA 1992*)* are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

Any person may file a notice of objection[5] regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of the Health Canada's website (Request a Reconsideration of Decision) or contact the PMRA's Pest Management Information Service.

[5] As per subsection 35(1) of the *Pest Control Products Act.*